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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,437	12/17/2001	Stephen A. Johnston	5171-00041	2358

7590 03/10/2010

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EXAMINER	
FORD, VANESSA L	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
03/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN A. JOHNSTON, KATHERINE STEMKE-HALE,
KATHRYN F. SYKES, and BERNHARD KALTENBOECK

Appeal 2009-006341
Application 10/023,437
Technology Center 1600

Oral Hearing Held: January 14, 2010

Before TONI R. SCHEINER, DEMETRA J. MILLS, and
FRANCISCO C. PRATS, Administrative Patent Judges

ON BEHALF OF THE APPELLANTS:

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The above-entitled matter came on for hearing on Thursday, January 14, 2010, commencing at 9:46 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Kevin E. Carr, Notary Public.

THE USHER: Calendar number 47, Appeal number 2009-006341.

Mr. McBride.

JUDGE SCHEINER: Thank you. Good morning. We're all anxious to hear how this organism is -- this species name is pronounced.

MR. MCBRIDE: Chlamydia psittaci.

JUDGE SCHEINER: Psittaci, okay.

MR. MCBRIDE: Or psittaci, or psittaci.

JUDGE SCHEINER: All right. Well, we all guessed wrong.

MR. MCBRIDE: Well, you know, actually, I had to look it up on the internet, actually had the pronunciation --

JUDGE SCHEINER: Oh, okay.

MR. MCBRIDE: I prepared some benchbook materials. I don't -- that might help.

JUDGE SCHEINER: Are these things that are already in the record?

MR. MCBRIDE: They're already in the record.

JUDGE SCHEINER: Okay. That's fine then, but we'll hand them back to you when we're done.

MR. MCBRIDE: Okay, that's fine. Let me just --

JUDGE SCHEINER: We're not going to enter them into the file. Okay, thank you.

JUDGE PRATS: Thank you.

JUDGE SCHEINER: We do actually have everything up here on our screens, so --

MR. MCBRIDE: Oh, okay. Okay, good. And you have to excuse my -- I'm a novice at this.

JUDGE PRATS: That's okay. Yeah, basically what we're --

THE REPORTER: I need you to be by the podium.

MR. MCBRIDE: Oh, okay. All right.

THE REPORTER: It's for the microphone.

MR. MCBRIDE: Oh, thank you.

JUDGE SCHEINER: Okay. Well, whenever you're ready, we're ready.

MR. MCBRIDE: Okay. Well, the question that the Appellants have asked the Board to address is whether or not the specification provides enablement for a method of immunizing an animal in an effective -- amount effective to induce an immune response against chlamydia psittaci, wherein the chlamydia psittaci antigen comprises the amino acid or polypeptide sequences as set forth in sequence ID number 7. There's also further dependent claims where additional antigens are administered in the immunization method.

The Office's position is that while the specification is enabled for a method of immunizing an animal in amount effective to induce an immune response against chlamydia psittaci wherein the chlamydia psittaci antigen comprises a mixture of antigens, the specification is not enabled for a method of administering a single antigen.

JUDGE SCHEINER: Can I interrupt you right here, please? Those -- these antigens represented by seq ID number 7, 9, 13, how are they related? Are they overlapping parts of the same protein? Are they different proteins from this organism or --

MR. MCBRIDE: They're overlapping. Initially all of these antigens were identified as fragments using a method called expression library immunization.

JUDGE SCHEINER: Mm-hmm, sure.

MR. MCBRIDE: So basically they identified various fragments and they were given original sequence ID numbers. Subsequently those fragments were compared to the completed genome of chlamydia pneumoniae, and then the full length genes were identified. And those were -- those sequence ID numbers were also presented. So for instance, sequence ID number 7 is the originally identified fragment using the expression library immunization.

JUDGE SCHEINER: Okay.

MR. MCBRIDE: Sequence ID number 9 is the full length gene that encompasses that fragment.

JUDGE SCHEINER: Okay. So 7 is embedded in 9 then.

MR. MCBRIDE: Exactly.

JUDGE SCHEINER: Okay.

MR. MCBRIDE: Right. And the same thing for the polynucleotide 6 and 8. And so if you look at table 3 it correlates all the different fragments.

JUDGE SCHEINER: Okay, okay. Thank you.

JUDGE MILLS: Your claims are only intended to cover the amino acids? They're not -- they do not cover the nucleic acids --

MR. MCBRIDE: That's correct. That's correct. And that's one of the issues that I think is -- that needs to be addressed as well. The Office has raised that issue, that our -- we're claiming a method of administering an antigen. We have examples where we've administered DNA. We do have examples where we've administered a mixture of the antigens, but they would like you to decide whether or not we're enabled for a method of administering a single antigen in view of that.

JUDGE MILLS: Okay.

MR. MCBRIDE: So we have several examples in the specification. One example -- well, let me back up. Initially 14 clones -- of all the clones that were synthesized in the library, 14 clones were narrowed down. Those were administered individually as DNA in a mouse model, a mouse -- what they call the lung weight increase model. They correlated that lung weight increase with disease and fatality, and administered various controls. They had non-vaccinated. They had an animal that was vaccinated with a low dose of --

JUDGE SCHEINER: Is that what we're seeing in figure 5?

MR. MCBRIDE: That's figure 5, yes. So yeah, if you look at figure 5, you could see that a number of the individual genes were effective at inducing a -- what they characterize as a protective response compared to the positive controls. In particular the -- what they called CP-4 number 1, which correlates with sequence ID number 6, which encodes the polypeptide of sequence ID number 7. And in fact they identified at least five that were

as good or better than the animals that were vaccinated with the low dose live chlamydia psittaci.

Subsequently to performing that experiment they also administered the mixture of all 14 clones into bovine, in a bovine infertility model, and found that that mixture was efficacious. Those results are presented in example 8. And then they did some sequence analysis and identified the full length genes that corresponded to the five most protective fragments, synthesized the genes for those full length genes, and used -- they were optimized for expression in mammalian cells. They also expressed the polypeptides corresponding to those and then administered either a mixture of the five genes or a mixture of the five polypeptides in a bovine infertility model as well.

So those were the basic examples that they used in the specification to try and justify enablement for the scope of the claims. I guess one thing that I would point out is that the Office has hammered home that the claims -- it's their position that the claims aren't limited to -- aren't enabled for administering a single antigen. But our claims actually are open ended. They're -- use comprising language. So it says it -- comprising sequence ID number 7, so they're not so limited. In addition, we have dependent claims where additional antigens are administered and they haven't -- they haven't addressed what would be sufficient I guess for -- in order to be enabled.

JUDGE SCHEINER: Maybe I'm looking at something wrong here, but do we have a 101 here?

MR. MCBRIDE: There is a 101 that relates to the fact that the Examiner would like us to recite that the antigen is an isolated antigen or a purified antigen --

JUDGE SCHEINER: Oh, okay.

MR. MCBRIDE: -- for statutory subject matter purposes.

JUDGE SCHEINER: I see.

MR. MCBRIDE: And yeah, further to whatever decision is -- you arrive at, we would amend the claims to -- accordingly to address that issue.

JUDGE SCHEINER: Okay.

MR. MCBRIDE: There's also a 112, second paragraph issue that we intend on addressing after -- after this --

JUDGE SCHEINER: Okay.

JUDGE PRATS: He's actually answered all the questions I was going to ask anyway, so --

JUDGE SCHEINER: Yeah, me too.

JUDGE MILLS: Right. I --

JUDGE SCHEINER: I don't know if you have anything further, but --

JUDGE PRATS: I have nothing.

MR. MCBRIDE: Okay, okay.

JUDGE SCHEINER: I think we understand the issue.

MR. MCBRIDE: Okay, great. Thanks a lot, appreciate it.

JUDGE SCHEINER: Okay. I think we probably --

Whereupon, at 9:52 a.m., the proceedings were concluded.